



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1068]

Orange Book--Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Orange Book--Questions and Answers.”

This guidance is intended to assist interested parties (including prospective drug product applicants, drug product applicants, and approved application holders) in utilizing the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book). This guidance finalizes the draft guidance of the same title issued on June 1, 2020.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or

confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2020-D-1068 for “Orange Book--Questions and Answers.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document. FOR FURTHER INFORMATION CONTACT: Susan Levine, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993-0002, 240-402-7936, Susan.Levine@fda.hhs.gov. SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Orange Book--Questions and Answers.” This guidance is intended to assist interested parties (including prospective drug product applicants, drug product applicants, and approved application holders) in utilizing the Orange Book. This guidance provides answers to commonly asked questions FDA has received from interested parties regarding the Orange Book.

The Orange Book identifies drug products approved by FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and related patent and exclusivity information. The main criteria for the inclusion of a drug product in the Orange Book are that the drug product is the subject of an approved application and that FDA has not determined the drug product to have been withdrawn from sale for safety or effectiveness reasons. In addition, the Orange Book contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to State health agencies, prescribers, and pharmacists to promote public education on drug product selection and to foster containment of healthcare costs.

This guidance provides answers to questions that have been received by FDA staff that manage the Orange Book. The questions and answers cover the following topics: general inquiries about the content and format of the Orange Book, petitioned abbreviated new drug applications, the movement of drug products between different sections in the Orange Book, and patent listings.

This guidance finalizes the draft guidance entitled “Orange Book--Questions and Answers” issued on June 1, 2020 (85 FR 33167). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include minor clarifying revisions (including revisions to reflect the Orange Book Transparency Act of 2020 enacted on January 5, 2021) (Pub. L. 116-290).

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Orange Book--

Questions and Answers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The following collections of information have been approved under OMB control number 0910-0001: (1) 21 CFR 314.50(a) through (f), (i), (h), and (k); (2) 21 CFR 314.53 for new drug application (NDA) submissions; (3) amendments to NDA submissions; (4) supplements to NDA submissions to FDA using Forms FDA 3542 (Patent Information Submitted Upon and After Approval of an NDA or Supplement) and 3542a (Patent Information Submitted With the Filing of an NDA, Amendment, or Supplement); and (5) 21 CFR 314.94.

In addition, the FDA Reauthorization Act of 2017 (Pub. L. 115-52) added section 506I to the FD&C Act (21 U.S.C. 356i), which imposes marketing status reporting requirements for notification of withdrawal from sale, notification of drugs not available for sale, and reports on marketing status. The collections of information regarding 506I notifications described in FDA’s guidance entitled “Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act” have been approved under OMB control number 0910-0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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